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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/819,669	03/17/97	BOON	T LUD-5253.5-D

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EXAMINER

CUNNINGHAM, T

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

03/17/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/819,669

Applicant(s)

Boon et al.

Examiner

Thomas Cunningham

Group Art Unit

1644



☒ Responsive to communication(s) filed on Dec 9, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 173-181 is/are pending in the application.

Of the above, claim(s) 177 and 178 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 173-176 and 179-181 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 173-181 are pending.
2. Applicant's election without traverse of Group I, claims 173-177 as directed to the MAGE-1 tumor rejection antigen precursor encoded by SEQ ID NO: 8 in Paper No. 8 is acknowledged. Applicant has indicated that claims 173 and 174 are generic, that claim 177 is subgeneric and that claim 175 is drawn to MAGE-1.

New claims 179-181 added by preliminary amendment are directed to compositions of matter encompassing the isolated tumor rejection antigen precursor of claim 173. These are considered part of the elected invention and will be examined to the extent that they encompass MAGE-1 (SEQ ID NO: 8).

Claims 177-178 and the generic and subgeneric claims as they read on nonelected proteins are withdrawn from consideration.

3. Applicant is required to amend page 1 of the specification to include series numbers, e.g. "07/" or "08/" before the appropriate application numbers.
4. Documents referred to in the specification have not been considered unless they appear in an information disclosure statement, form 1449 or have been cited by the Examiner on the PTO-892 form.

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5. Documents incorporated by reference into the specification are presumed not to contain essential subject matter as essential subject matter must be described within the specification itself.

6. Claims 179-181 are rejected under 35 U.S.C. 112, second paragraph as failing to particularly point and distinctly claim the invention.

A. It is unclear what the metes and bounds of the term “composition of matter” are. Is this limited to noncovalently associated ingredients, such as an isolated MAGE-1 antigen and an excipient such as PBS or normal saline? Is this term intended to embrace fusion proteins or protein conjugates comprising the MAGE-1 antigen, e.g. MAGE-1 conjugated to a protein carrier such as KLH or diphtheria toxoid? Is the term “composition of matter” intended to have a different scope or meaning than the term “composition” as conventionally used in biotechnology claim language?

B. It is unclear what the metes and bounds of the term “isolated” are. It is presumed that this encompasses MAGE-1 which is isolated from other antigens or tissue components which it is ordinarily associated, e.g. other tumor cell proteins or products. Does this term also require that the isolated MAGE-1 antigen not be covalently attached to another component, such as a carrier protein or effector component?

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C. In claims like claim 173-175 and 179-181, it is unclear what the metes and bounds of the claimed isolated tumor rejection antigen are. For instance, is the MAGE-1 protein of claim 175 limited to the full-length translate of SEQ ID NO: 8, or does it also encompass fragments encoded by a portion of SEQ ID NO:8? If SEQ ID NO: 8 is genomic DNA, then is the recited MAGE-1 protein limited to amino acid residues encoded by the MAGE-1 exons?

D. In claim 173 it is unclear whether the term “non tum-antigen” refers to a non-tum⁻ (minus) antigen. Is the dash “-” intended to be a superscript minus sign? See e.g. page 3 of the specification which refers to tum⁺ and tum⁻ antigens. Alternatively, does this hyphenated term refer to any non-tum antigen, whether a tum⁺ and tum⁻ antigen?

7. Claim 176 is rejected under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed tumor rejection antigen, MAGE-1. While claim 176 indicates that the MAGE-1 antigen may be encoded by a variety of different nucleotide sequences, it is the same MAGE-1 antigen as claimed in claim 175. The MAGE-1 antigen to which both these claims are directed is the same antigen whether encoded by the nucleotide sequence of SEQ ID NO:8 or by a different, yet redundant nucleotide sequence which encodes the same amino acids forming the MAGE-1 polypeptide.

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8. Claim 181 is rejected under 35 U.S.C. 112, fourth paragraph as failing to further limit the ingredients of the claimed composition. The recited components of the composition of matter of claim 181 are no different than those recited by claim 179 from which it depends.

9. The following documents contain 100% matching sequences to SEQ ID NO:8.

WO 94/23031-A published 13-Oct-1994, Boon-Falleur et al. (Not prior art)

WO92/20356-A, published 26-Nov-1992, Boon et al. (Not prior art)

WO95/20974-A, published 10-Aug-1995. Boon-Falluer et al. (Not prior art)

U.S. patent 5,541,104, published 30-Jul-1996, filed 01-Feb-1994. Chen et al. (Not prior art)

Science 254:1643-1647, published 13-Dec-1991. Van der Bruggen et al. (Not prior art)

10. A comparison of instant SEQ ID NO: 8 and the MAGE-1 amino acid sequence set forth in Fig. 6B of U.S. patent appears to indicate that the two sequences are identical. Therefore, for the purposes of determining both priority and prior art issues it is assumed that the MAGE-1 amino acid sequence disclosed by each claimed priority document is the same as the amino acid sequence of MAGE set forth by SEQ ID NO: 8. If any originally disclosed MAGE-1 amino acid sequence has been modified or corrected the Applicant is requested to notify the Examiner of the correction and date the correction was made.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TC

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